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STATE PASS TO USTR (CROWDER, BISBEE, CLARKSON)  
USDA FOR DUS TERPSTRA  
USDA PASS TO FAS (OA, OSTA, ONA, OCRA, OFSO)  
TREASURY FOR OASIA

E.O. 12958: N/A

TAGS: [EAGR](#) [ETRD](#) [WTRO](#) [TBIO](#) [USTR](#) [VM](#)

SUBJECT: Draft Biotech Regulations Could Hamper Trade

HANOI 00000064 001.2 OF 004

¶1. Summary. This cable provides translation of Vietnam Food Administration's latest draft biotechnology regulations, which are expected to be formally notified to the WTO soon. On their face, the regulations could hamper or restrict U.S. exports of biotech products. Post would welcome comments from Washington to share with Vietnamese officials. End Summary.

¶2. Vietnam Food Administration, (VFA) the regulatory agency under the Ministry of Health that oversees food safety, recently shared with FAS/Vietnam the tenth draft of its regulations governing the import and trade of biotech foods. FAS/Vietnam has had the draft regulations translated into English (see full text in para 5). Although VFA has not specifically solicited comments, Post encourages comments from FAS and other relevant USG agencies because we believe they would be of interest to VFA. Post understands that Vietnam will formally notify these draft regulations to the WTO within a week.

¶3. It appears to Post that these draft regulations were written from a standpoint of an underlying distrust of biotech foods; hence the provisions for seemingly excessive surveillance and safeguards. Importers and traders are being subjected to undue and unreasonable requests for possible proprietary information as well as special licenses in order to conduct trade.

¶4. These draft regulations appear to apply to bulk commodities as well as processed foods, two areas where U.S. export trade has experienced considerable growth over the last year. Approval and implementation of these regulations could have a deleterious effect on our trade. Particularly troubling are the demands for confirmation outlined in Chapter III as well as the trade and labeling requirements of Chapter IV. It would appear from item 2 of Article 9 that a special license is required to engage in trade of GM foods.

¶5. BEGIN TEXT

REGULATIONS ON MANAGEMENT OF SAFETY AND HYGIENE OF FOOD ORIGINATED FROM GENE-MODIFIED ORGANISM  
(Issued in conjunction with Decision /2007/QD-BYT dated 2007  
of the Minister of Health)

## CHAPTER I: GENERAL PROVISIONS

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### ARTICLE 1: SCOPE OF APPLICATION

1) These Regulations stipulate the management of safety and hygiene of food originated from gene-modified organisms produced in the country or imported to be circulated and sold in Vietnam, including the following products (collectively called gene-modified food).

a) Materials being gene-modified food which has been industrially processed without re-refining in order to be used for direct productions, packed or re-packed;

b) Packed food for direct use, which contains gene-modified ingredients;

2) The following gene-modified food shall not be regulated by these regulations:

a) Fresh or primarily treated gene-modified food falling within the list subject to plant and animal quarantine;

b) Gene-modified food being test or research samples;

c) Gene-modified food being sample in fairs;

d) Gene-modified food being agriculture products imported and exported;

### ARTICLE 2: SUBJECTS OF APPLICATION

These regulations shall be applicable to organizations and individuals who produce, trade and import gene-modified food as stipulated in Clause 1, Article 1 of these regulations.

### ARTICLE 3: EXPLANATION OF WORDS AND EXPRESSION

In these regulations, some words and expression shall be construed as follows:

1) Gene-modified food is the food originated from gene-modified organisms or the ingredients of the food which are originated from gene-modified organisms.

2) Gene modified materials shall be the materials obtained from gene-modified organisms, which are used for production of products and which exist in the finished products even the form of the materials is already changed.

HANOI 00000064 002.2 OF 004

3) Labeling gene-modified food is to express the basic and necessary contents of the gene-modified food on the label of products so that consumers can identify, use them as basis to select and use; so that producers and traders advertise their products and so that the functional agencies conduct examination, inspection and supervision.

4) Biological safety requirements with respect to gene-modified food mean ensuring that gene-modified materials used for production of gene-modified food must be subject to risk assessments in order to minimize or reject gene-modified materials, which cause danger of toxicity or allergy to people's health; danger of adverse impacts on the environment and biological diversification.

5) Hygiene and safety requirements with respect to gene-modified food means ensuring that gene-modified food is produced at establishments satisfying the hygiene and safety requirements in accordance with the regulations and not affecting to nor harming people's health.

6) Danger of affecting to people's health of gene-modified food is the possibility of causing allergy and toxicity or special constituents being toxicity or instability of transplanted gene or efficiency of increasing the nutrition content or any effect occurs due to transplanting new gene.

### ARTICLE 4: GENERAL REQUIREMENTS

1) Gene-modified food products circulated or sold in the market must satisfy the following requirements:

a) Safety for people's health;

b) Being labeled in accordance with Article 11 of these regulations;

c) Complying the periodical inspection in accordance with the current regulations;

2) Name of establishments producing and trading gene-modified food must:

a) Have certificate on satisfaction of hygiene and safety requirements with respect to other food of high danger.

b) Archiving goods' dossiers and other report documents relating to

gene-modified food for 5 years and being ready to provide them at the request of the competent State body.

## CHAPTER II: REGULATIONS APPLICABLE TO GENE-MODIFIED FOODS WHICH ARE LOCALLY PRODUCED

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### ARTICLE 5: HYGIENE SAFETY REQUIREMENTS OF LOCALLY-PRODUCED GENE-MODIFIED FOOD PRODUCTS

Before circulated and sold in the market, locally produced gene-modified food must satisfy the following requirements:

- 1) Having assessed the danger.
- 2) Having certificate on safety of ingredients of gene-modified food issued by the Ministry of Agriculture and Rural Development.

### ARTICLE 6: ANNOUNCEMENT OF THE STANDARDS OF LOCALLY PRODUCED GENE-MODIFIED FOOD

Apart from implementation of regulations on announcement of the products' standards on gene-modified food in accordance with the current regulations, organization and individuals who produce and trade gene-modified food must provide the following information:

- 1) Name of gene-modified food products;
- 2) Name of transplanted gene: purpose, position, characteristics, stability of transplanted gene;
- 3) Having certificate on safety:
  - a) Non-allergy
  - b) Not creating toxicity affecting to the people's health;
  - c) Nutrition composition and substances;
  - d) Stability of transplanted gene.

## CHAPTER III: REGULATIONS APPLICABLE TO IMPORTED GENE-MODIFIED FOOD

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### ARTICLE 7: HYGIENE SAFETY REQUIREMENTS OF IMPORTED GENE-MODIFIED FOODS

Gene-modified food imported into Vietnam to circulate or be sold in the market must satisfy the following requirements:

- 1) Exporting country permits it to circulate nationwide;
- 2) The danger (of the food) has been assessed;
- 3) Having a Certificate on safety and test report with norms as issued by the competent body of exporting country;
- 4) Exporting country has established measures and regime for management of these products.

HANOI 00000064 003.2 OF 004

### ARTICLE 8: PROCEDURE FOR IMPORT

1) Imported gene-modified foods shall have to comply with the law on imported food and shall have to announce the products' standards at the Ministry of Health (Department of Food Safety and Hygiene). Besides, the exporting party shall have to provide the following information:

- a) Confirmation of non-danger of allergy (the transplanted gene has the safe origin)
  - b) Confirmation of no danger of creating toxicity;
  - c) Confirming that there is no anti-biotic resistance;
  - d) Report on confirmation of nutrition composition as compared with normal food;
  - e) Confirmation of stability of transplanted gene (until the sixth generation);
  - f) Ratio of GM-protein or GM-AND being modified in the food;
  - g) Name of transplanted gene: purpose, position, characteristics and stability of replacing gene.
- 2) In case where exporting country and Vietnam have signed an agreement on recognition of gene-modified food, (the procedure for import) shall be implemented in accordance with this agreement.

## CHAPTER IV: TRADING, ADVERTISEMENT, LABELING, SUPERVISION AND SUSPENSION OF CIRCULATION OF GENE-MODIFIED FOOD

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### ARTICLE 9: TRADING

- 1) Organizations and individuals shall only be permitted to trade gene-modified food when they have Certificate on product's standard of such gene-modified food;
- 2) Organizations and individuals shall only be permitted to trade

gene-modified food when they have a certificate on registration of business in this sector;  
3) Organizations and individuals producing and trading gene-modified food shall have to bear the responsibility before the law when they implement not in accordance with the registered criteria.

#### ARTICLE 10: INFORMATION AND ADVERTISEMENT

1) Organizations and individuals shall only be permitted to carry out advertisement when they have a Certificate on products' standards with respect to gene-modified food as issued by the Department of Food Safety and Hygiene.  
2) The advertisement of gene-modified food must comply with the advertisement regulations.

#### ARTICLE 11: LABELING

1) Labeling gene-modified food shall be conducted in accordance with the current regulations on Labeling domestically-circulated goods and imported, exported goods.

2) The contents of gene-modified food labeling shall be as follows:  
a) Gene-modified food is equivalent to normal food with respect to ingredients, nutrition value and content of substances.

##### PROCESSED FOOD:

Modified Protein left in products: Compulsory labeling. Modified DNA left in products: Compulsory labeling.

##### PROCESSED FOOD:

Modified Protein not left in products: not subject to compulsory labeling.

Modified DNA not left in products: Not subject to compulsory labeling.

b) Gene-modified food is different from normal food with respect to ingredients, nutrition value and content of substances.

##### COMPULSORY LABELING:

c) Example of labeling:

With respect to foods containing only one ingredient, the words "gene-modified" must be recorded with the name of the product or must be put into brackets right after the name of gene-modified ingredient as listed in the composition.

##### GENE-MODIFIED MAIZE OR MAIZE (GENE-MODIFIED):

With respect to foods containing more than one ingredient, the label of the product must be recorded with words of "gene-modified" together with name of the gene-modified ingredient or must be put into brackets right after the name of gene-modified ingredient as listed in composition.

Composition: Skimmed milk powder; maize starch (gene-modified); glucose; soy-bean powder; citric acid; Salt; Vegetable oil; Vanilla Flavoring.

3) The contents as announced in the label must be put at the position so that they can be realized easily and they must be

HANOI 00000064 004.2 OF 004

presented clearly, straightforward, readably with naked eye, and the dimensions and space of words must be reasonable, the size of the words must equal to the size of words of ingredient names.

#### ARTICLE 12: SUPERVISION

1) State body in charge of food hygiene and safety shall supervise gene-modified food being circulated and sold in the market.

2) Organizations and individuals shall be responsible for notifying the State body in charge of issuance of Certificate on products' standards with respect to gene-modified food any technical information or newly applied science, which affects to the safety of constituents used in processing food and prohibition or limitation relating to gene-modified food.

#### ARTICLE 13: SUSPENSION OF CIRCULATION

Suspension of circulation of gene-modified food shall be implemented in accordance with the current regulations as applicable to other normal products. Besides, inspecting and examining body shall announce to return or withdraw gene-modified food if any one of the following issues happens:

1) Gene-modified foods is declared as gene-modified one, however, the gene-modified element is discovered contrary to what has been registered.

2) Gene-modified food is declared as not gene-modified one, however, the gene-modified element is discovered after inspection.

3) When there is evidence of management body that gene modified food

already issued with a Certificate on products' standards with respect to gene-modified food has danger to people's health, animals' health and the environment, the Certificate on products' standards must be suspended or amended promptly.

## CHAPTER V: IMPLEMENTATION PROVISIONS

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### ARTICLE 14: ORGANIZATION OF IMPLEMENTATION

- 1) Department of Food Safety and Hygiene - the Ministry of Health shall be responsible for carrying out, examining, inspecting and supervising the implementation of these regulations;
- 2) Health Departments of provinces and cities under central authorities, relevant health agencies shall be responsible for organizing the implementation, directing, inspecting, examining and supervising units producing and trading gene-modified foods during the course of implementation of these regulations.
- 3) Organizations and individuals producing, trading and importing gene-modified food shall be responsible for implementation of these regulations.

### ARTICLE 15: DEALING WITH BREACHES

Organizations and individuals committing breaches of these regulations shall be subject to disciplinary measures, administrative penalty or investigation for criminal responsibility. If they cause damage they shall have to make compensation for damage in accordance with the law.

END TEXT

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